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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Subramaniam Srikumaran

Art Unit 1648

Serial No. 10/003,907

Filed November 2, 2001

Confirmation No. 7717

For METHODS AND COMPOSITIONS FOR PROTECTION AGAINST BOVINE
VIRAL DISEASES

Examiner Bao Qun Li

UNL 3060.2

Patent

1648

#6

Election

02/27/03

February 14, 2003

RESPONSE TO RESTRICTION REQUIREMENT

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS,
SIR:

This letter is in response to the Office action mailed January 16, 2003 (Paper No. 5).

For purposes of examination, the Office has required the Applicant to elect one of the following: claims 1-21 (drawn to a method of eliciting an immune response), or claims 22-39 (drawn to a composition comprising purified epitope/heat shock protein complex). In addition, irrespective of the group elected, the Applicant has been required to elect a single allele specific peptide motif, a single viral epitope, and a single heat shock protein; the Office further notes that this election **is not** to be construed as a requirement for an election of species.

Applicant does not traverse the restriction of claims 1-21 (Group I) from claims 22-39 (Group II). Applicant does, however, traverse the Office's refusal to treat the requirement for election as "an election of species."

The Office's refusal to treat the requirement for election as "an election of species," is tantamount to a denial of generic protection for the invention defined by claims 1-21. These claims generically define a method of eliciting an immune response

against a bovine virus comprising administration of a combination of at least one bovine viral epitope and at least one heat shock protein to form a purified epitope/heat shock complex. There are many different bovine virus species. Additionally, there are many epitopes (*i.e.*, antigenic determinants) within any given bovine virus. There are also a number of heat shock proteins. As such, the number of potential combinations is quite large. But yet, the Office has indicated with this restriction requirement that each combination of a single epitope and a single heat shock protein represents an independent and distinct invention, thereby requiring Applicant to elect among what would be numerous possible combinations thereof. Extending this approach to its logical conclusion, Applicant would be forced to file an incredible number of patent applications, at an unimaginable and clearly unaffordable cost, to obtain anything even approximating generic protection.

Applicant's specification generically enables a method of eliciting an immune response against a bovine virus. If the claims of a patent were restricted to one and only one epitope/heat shock protein combination, therefore, a competitor, armed with Applicant's teaching, could avoid infringement of this patent by simply selecting another combination. And, since Applicant could not possibly afford to file a separate patent application for each and every combination, Applicant would be left without a remedy despite the fact that the infringer would be using the novel approach described in Applicant's specification and presently defined by claim 1. Without generic claims, therefore, any protection for Applicant's invention is effectively eviscerated.

Further, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions."¹ No showing has been made by the Office that the search and examination of this entire application, or at least something less than the three cited groups, will impose a serious burden upon the

¹MPEP § 803, emphasis added. See also, § 803.02.

Office. The proper course, therefore, would be to require an election of species as to the allele specific peptide motifs of claim 4 or 25, the viral epitope of claim 8 or 29, and the heat shock proteins of claim 9 or 30; an "[e]lection of species should be required prior to a search on the merits . . . in all applications containing both species claims and generic or Markush claims." MPEP § 808.01(a). See also, MPEP § 809.02 and 37 C.F.R. 1.146.

Subject to the foregoing traverse, Applicant elects Group I for examination, electing BoLA-A11 as the allele specific peptide motif, bovine respiratory syncytial virus as the viral epitope, and HSP 90 as the family of heat shock proteins, and, should the Office intend with this restriction requirement that a specific heat shock protein be elected (this is unclear), gp96 as the specific heat shock protein within the HSP 90 family of heat shock proteins. Applicant makes such an election without prejudice to the patentability of the non-elected claims, and expressly reserve the right to file a divisional application directed to these claims.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 19-1345.

Respectfully submitted,



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